UNITED STATES DISTRICT COURT DISTRICT OF MAINE

UNITED STATES OF AMERICA,)
v.) Docket No. 2:22-cr-00132-NT
MERIDETH C. NORRIS, D.O.,)
Defendant)

ORDER ON DEFENDANT'S MOTIONS TO DISMISS

Before me are two motions to dismiss the indictment brought by the Defendant (ECF Nos. 65, 66). For the reasons stated below, both motions are **DENIED**.

FACTUAL BACKGROUND

The Defendant, Merideth C. Norris, D.O., is licensed in osteopathic medicine and focuses her practice on pain management. Def.'s Mot. to Dismiss (Vagueness) ("First Mot.") 1 (ECF No. 65). On October 20, 2022, a grand jury returned an indictment charging Dr. Norris with ten counts of distribution of a controlled substance in violation of 21 U.S.C. § 841(a)(1) ("Section 841"). Indictment 2 (ECF No. 3). On September 7, 2023, the grand jury returned a superseding indictment charging Dr. Norris with seventeen counts of distribution of a controlled substance in violation of Section 841 and 18 U.S.C. § 2. Superseding Indictment 2 (ECF No. 62). The seventeen counts relate to seventeen prescriptions Dr. Norris allegedly made out for five different patients. See Superseding Indictment 2–3.

STATUTORY BACKGROUND

Congress enacted the Controlled Substances Act ("CSA") in 1970 with the purposes of "combating drug abuse and controlling the legitimate and illegitimate traffic in controlled substances." *Gonzales v. Oregon*, 546 U.S. 243, 250 (2006). It "create[d] a comprehensive, closed regulatory regime criminalizing the unauthorized manufacture, distribution, dispensing, and possession of substances classified in any of the Act's five schedules." *Id.* The CSA makes it unlawful for anyone to knowingly or intentionally distribute or dispense controlled substances "[e]xcept as authorized." 21 U.S.C. § 841.

Congress authorized the Attorney General to "promulgate rules and regulations . . . relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances." 21 U.S.C. § 821. The Attorney General may also "promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution" of his registration and control functions. 21 U.S.C. § 871(b). The Attorney General delegated the registration authority to the DEA. 21 U.S.C. § 871(a) (authorizing the Attorney General to delegate any of his functions "to any officer or employee of the" DOJ); 28 C.F.R. 0.100(b).

To prevent diversion of controlled substances with valid medical purposes, the CSA also regulates physicians. To dispense controlled substances, a physician must first obtain a registration from the DEA "in accordance with the rules and regulations promulgated" under its registration authority. 21 U.S.C. § 822; 21 C.F.R. §§ 1301.11–12. The CSA requires the DEA to register physicians who are authorized to dispense

controlled substances "under the laws of the State in which [s]he practices." 21 U.S.C. § 823(g); see id. § 802(21) (defining "practitioner" as a "physician . . . or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which [s]he practices . . . , to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice"). The DEA may also deny, revoke, or suspend a doctor's registration if, for example, the doctor committed acts that would render her registration "inconsistent with the public interest." Id. § 824(a)(4); see id. § 823(g)(1)(D) (enumerating public interest factors such as "compliance with applicable State, Federal, or local laws relating to controlled substances").

Once registered, a doctor is only "authorized" to prescribe controlled substances "to the extent authorized by their registration and in conformity with the other provisions" of the CSA. 21 U.S.C. § 822(b). A prescription is "authorized" if the prescriber issues it "for a legitimate medical purpose . . . acting in the usual course of [her] professional practice." 21 C.F.R. § 1306.04(a). The language of this regulation tracks that in 21 U.S.C. § 829, which defines a "valid prescription" as "a prescription that is issued for a legitimate medical purpose in the usual course of professional practice" by a qualifying practitioner. 21 U.S.C. § 829(e)(2)(A).

DISCUSSION

The Defendant now moves to dismiss the Superseding Indictment in two separate motions. First, she argues that the case against her should be dismissed because Section 841 is unconstitutionally vague as applied to her as a physician. First

Mot. 2. Second, she argues for dismissal on the grounds that Congress never gave authority to the Attorney General, Department of Justice, or Drug Enforcement Administration ("**DEA**") to define when a physician is not "authorized" to prescribe controlled substances under Section 841, and thus the Government cannot bring a case against her. See Def.'s Mot. to Dismiss (Exceeding Congressional Authority) 2–3 ("**Second Mot.**") (ECF No. 66). I address each of these motions in turn below.

I. Vagueness

In her first motion, Dr. Norris argues that Section 841 of the CSA is void for vagueness. Section 841 provides that, "[e]xcept as authorized . . . , it shall be unlawful for any person knowingly or intentionally . . . to manufacture, distribute, or dispense[] . . . a controlled substance." 21 U.S.C. § 841(a)(1). As discussed above, an exception exists for registered doctors who prescribe controlled substances provided the prescription is "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a); see Ruan v. United States, 597 U.S. 450, 454 (2022). According to the Defendant, Section 841 and 21 C.F.R. § 1306.04(a) are unconstitutionally vague as applied to her conduct. First Mot. 10; Reply to Opp'n to Mot. to Dismiss (Vagueness) ("First Reply") 5 (ECF No. 89).

"The vagueness doctrine, a derivative of due process, protects against the ills of laws whose prohibitions are not clearly defined." *March v. Frey*, 458 F. Supp. 3d 16, 39 (D. Me. 2020) (quoting *Nat'l Org. for Marriage v. McKee*, 649 F.3d 34, 62 (1st Cir. 2011)). "A statute is impermissibly vague if it 'fails to provide a person of ordinary intelligence fair notice of what is prohibited, or is so standardless that it authorizes

or encourages seriously discriminatory enforcement." Frese v. Formella, 53 F.4th 1, 6 (1st Cir. 2022) (quoting United States v. Williams, 553 U.S. 285, 304 (2008)). Fair notice does not require a statute to "map out what is prohibited with 'meticulous specificity.' . . . It must only 'delineate its reach in words of common understanding.'" Id. at 12 (quoting Grayned v. City of Rockford, 408 U.S. 104, 110, 112 (1972)).

The Defendant concedes that her vagueness challenge to the CSA and its regulations is an as-applied challenge. First Reply 5.

Outside of the First Amendment context, we consider "whether a statute is vague as applied to *the particular facts at issue*," for a defendant "who engages in some conduct that is clearly proscribed cannot complain of the vagueness of the law as applied to the conduct of others."

United States v. Zhen Zhou Wu, 711 F.3d 1, 13 (1st Cir. 2013) (quoting Holder v. Humanitarian L. Project, 561 U.S. 1, 18–19 (2010)). Because the inquiry is fact-bound, courts consider it premature to decide vagueness challenges to criminal statutes before the facts are developed at trial. See United States v. Craigue, No. 19-cr-142-LM, 2020 WL 1027818, at *4 (D.N.H. Mar. 3, 2020); United States v. Thompson, 207 F. Supp. 3d 106, 112 (D. Mass. 2016); United States v. Harris, No. CR 09-10243-MLW, 2012 WL 2402788, at *3 (D. Mass. June 26, 2012); United States v. Adelglass, No. 20-cr-605 (JSR), 2022 WL 6763791, at *3 (S.D.N.Y. Oct. 11, 2022) (denying doctor's motion to dismiss indictment charging him with violating Section 841 on vagueness grounds because the motion needed to be decided based on evidence at trial rather than the allegations in the indictment); United States v. Reed, 114 F.3d 1067, 1070 (10th Cir. 1997).

This case hinges on whether Dr. Norris "knowingly or intentionally acted in an unauthorized manner" by prescribing controlled substances. *See Ruan*, 597 U.S. at 457. Although the Government proffers what it claims the evidence will be at trial, Dr. Norris disputes many of these facts and the inferences to be drawn from them. *See* Gov't's Opp'n to Def.'s Mot. to Dismiss (Vagueness) ("Gov't's Opp'n") 2–4 (ECF No. 82); First Reply 5. The motion to dismiss on grounds of vagueness cannot be decided without further factual development, and, accordingly, it is denied without prejudice to Dr. Norris renewing her vagueness argument following the close of the evidence at trial.

II. Exceeding Congressional Authority

In her second motion, Dr. Norris argues for dismissal on the theory that Congress never delegated power to the DOJ, Attorney General, or DEA to criminalize conduct by defining when physicians are "authorized" to dispense controlled substances under Section 841. Second Mot. 3. The Defendant essentially makes three arguments. First, she contends that "[w]hat conduct falls within the authorization" contemplated by Section 841 is "clear as mud." Second Mot. 2. Second, the Defendant argues that the Attorney General and the DEA have exceeded their authority and usurped the State's authority by defining what should constitute the authorized practice of medicine. Second Mot. at 3. Finally, the Defendant contends that the delegation of rule-making authority to the Attorney General found in Section 821 is "neither sufficiently clear nor adequately explicit" to assure that Congress intended to allow the Attorney General or his delegee, the DEA, to criminalize a physician's conduct. Second Mot. at 3. I address the Defendant's arguments in turn.

First, the Defendant, citing Ruan v. United States, 597 U.S. 450 (2022), contends that the language of Section 1306.04(a) is fatally ambiguous. In Ruan, the Government brought criminal prosecutions under Section 841 against two physicians accused of writing unauthorized prescriptions. The Supreme Court vacated the convictions of the physicians and remanded for further proceedings because the jury instructions did not convey that the Government had to prove that the physician knowingly or intentionally acted in an unauthorized manner. Id. at 468. The Defendant highlights Ruan's statement that the language of Section 1306.04 is "vague, highly general," "ambiguous, written in generalities, susceptible to more precise definition and open to varying construction." Second Mot. 2 (quoting Ruan, 597 U.S. at 459, 464). The Defendant's argument largely rehashes her vagueness argument, which I have tabled as premature, but it is interesting to note that although the Supreme Court recognized the gray area in the phrases "legitimate medical purpose" and "usual course of . . . professional practice," it went on to assert that these are "objective criteria." Ruan, 597 U.S. at 467. Ruan certainly does not stand for the proposition that the ambiguity in Section 1306.04 is fatal to a criminal prosecution of a physician. United States v. Sadrinia, No. 22-28-DLB-CJS, 2023 WL 3854054, at *2 (E.D. Ky. June 6, 2023) (Ruan "noted the ambiguity in [Section 1306.04(a)] and still went on to illuminate the scienter requirement as the appropriate conclusion").

Defendant next argues that the Attorney General and DEA have exceeded their rulemaking authority and usurped the State's authority by attempting to define in Section 1306.04 when a physician's conduct is authorized. The Defendant takes an unattributed line out of the defendant's brief in *United States v. Sadrinia* when she argues that Section 1306.04(a) "places the DEA in the position of a de facto medical board, usurping the authority of state agencies and substituting the DEA's medical judgment for that of experienced practitioners (or state agencies)." Second Mot. at 3. What she neglects to say is that this argument was rejected by the court to which it was presented. In rejecting the defendant's usurpation argument, the court wrote: "The actual distinction between authorized and unauthorized conduct still lies at state level decision making because that conduct is determined in reference to the state laws and regulations in which the practitioner is prescribing the controlled substances. Sadrinia, 2023 WL 3854054, at *3 (citing Gonzales, 546 U.S. at 270 and 21 U.S.C. §§ 823(f), 808(21)). I agree with the court in the Eastern District of Kentucky. Here, state law and regulations will be considered to measure whether Dr. Norris's prescriptions were authorized; there is, at least on this record, no usurpation of the State's authority. See generally 02-373, 380, 383, 396 C.M.R. ch. 21 §§ 1–5 (the

In her reply to the Government's opposition, the Defendant takes issue with the Government's reliance on certain CDC guidelines from 2016 on opioid prescribing. See Reply to Opp'n to Mot. to Dismiss (Exceeding Congressional Authority) ("Second Mot.") 3–7 (ECF No. 88); Gov't's Opp'n to Mot. to Dismiss (Exceeding Congressional Authority) ("Gov't's Opp'n") 2–3 & nn. 2–3 (ECF No. 82). The Defendant states that the CDC guidance suggested that opioid prescriptions of more than 90 morphine milligram equivalents ("MME") were unnecessarily high. Second Mot. 3. She points out that the DOJ has been criticized for applying this standard too rigidly in prosecuting doctors. Second Mot. 3–6. And the Government concedes that the CDC updated the 2016 guidance in November of 2022 (after Dr. Norris issued the prescriptions in the Superseding Indictment), getting rid of a specific dosage threshold in favor of more flexible guideposts. Gov't's Opp'n 3 n.3.

While "there is no pat formula describing what proof is required to ground a finding that a defendant acted outside the usual course of professional practice," *United States v. Sabean*, 885 F.3d 27, 46 (1st Cir. 2018), Maine's laws and regulations are important to consider. The Maine Board of Osteopathic Licensure's rule on the use of controlled substances for treatment of pain establishes principles of proper pain management. These principles include that "[t]he dosage of the combination of opioid medication in an aggregate amount must not exceed 100 MME per day," subject to certain

Maine Board of Osteopathic Licensure's rule on the "use of controlled substances for treatment of pain").

The Defendant's argument that the Attorney General and the DEA have exceeded their authority under the CSA also relies on Gonzales. In Gonzales, the Court assessed the validity of an Interpretive Rule issued by the Attorney General that prohibited the use of controlled substances for physician-assisted suicide notwithstanding an Oregon law permitting the procedure. 546 U.S. at 253–54. The Court, concluding that the Interpretive Rule exceeded the bounds of the Attorney General's rule-making authority, determined that the CSA authorized the Attorney General to "promulgate rules relating only to 'registration' and 'control,' and 'for the efficient execution of his functions' under the" CSA but did not "delegate to the Attorney General authority to carry out or effect all provisions of the CSA" or to "regulate the practice of medicine generally." Id. at 259, 270. Key to the Supreme Court's holding in *Gonzales* was that the Attorney General issued its Interpretative Rule about physician-assisted suicide in direct opposition to a state law permitting the procedure. See id.; United States v. Lovern, 590 F.3d 1095, 1100 (10th Cir. 2009); United States v. Ahuja, 209 F. Supp. 3d 489, 495–96 (D. Conn. 2016); United States v. Bourlier, No. 3:10cr30/MCR, 2011 WL 30301, at *2 (N.D. Fla. Jan. 4, 2011); United States v. Hazelwood, No. 1:10 CR 150, 2011 WL 2565294, at *5 (N.D. Ohio June 27, 2011). No such concern is present here.

exceptions. 02-373, 380, 383, 396 C.M.R. \S 4(2)(B)(2)(d)(i). The Government alleges that "[a]t times, Defendant was issuing prescriptions with extremely high [MME] calculations, at times exceeding 1,000 MME." Gov't's Opp'n 2.

The Defendant makes the claim that "the State has expressly commended and licensed Dr. Norris's practice." Second Mot. 3. While it is uncontested that Dr. Norris was licensed by the State, the Defendant does not elaborate as to what she means when she says that the State "expressly commended" her practice. In connection with other motions, the parties both refer to a 2022 review of Dr. Norris by the Board of Osteopathic Licensure (the "Board"), but there is nothing in the record on this motion which sheds light on the specifics of the Board's review or findings. As such, I cannot find that the Government has charged Dr. Norris for issuing prescriptions that the Board has already found met state standards. Were that the case, Gonzales would be more on point. But since that does not appear to be the case at least for a large part of the conduct charged in the Superseding Indictment, see supra note 2, Gonzales does little to advance the Defendant's argument.

The Defendant has submitted, in connection with another motion, letters from the Board indicating that a complaint (related to Walmart refusing to fill Dr. Norris's prescriptions) was initiated against Dr. Norris and ultimately dismissed. See Letters from Susan E. Strout, Exec. Secretary, State of Maine Board of Osteopathic Licensure, to Merideth Norris, DO, dated June 16, 2022 and October 14, 2022 ("Board Letters") (ECF No. 73-1); Aff. of Amanda Mahan 2 & Ex. A (ECF No. 73-1). The June letter stated that "on February 10, 2022, the Board . . . voted to initiate a complaint against [Dr. Norris's] licensure" pursuant to 32 M.R.S. §§ 2591-A(2)(F) and (H). Board Letters, PageID #646; see 32 M.R.S. § 2591-A(2)(F) (providing that the Board may revoke or suspend a license if a licensee "engaged in unprofessional conduct," meaning that the "licensee violate[d] a standard of professional behavior that has been established in the practice for which the licensee is licensed"); 32 M.R.S. § 2591-A(2)(F) (providing that the Board may revoke or suspend a license for violating a Board Rule such as Chapter 21, Use of Controlled Substances for Treatment of Pain).

The Government mentioned in its opposition to a motion to suppress that the Board issued a subpoena for Dr. Norris's records on December 29, 2021, seeking "the production of 'complete medical records' for five patients, one of which was Patient 1 (as identified in the Superseding Indictment)." Gov't Opp'n to Def.'s Mot to Suppress 5 (ECF No. 86). Dr. Norris's prescriptions relating to Patient 1 that were written before December 29, 2021 (the date of the Board's subpoena) form the basis for Counts One and Two of the Superseding Indictment. So, while there may be some overlap between conduct reviewed by the Board and charged in the Superseding Indictment, it does not appear that the State reviewed the conduct that forms the basis of the remaining fifteen counts of the Superseding Indictment. Because the parties have not directly addressed this issue, it is difficult to say what, if any, overlap exists between the conduct that formed the basis of the complaint before the Board and the conduct that forms the basis of the Superseding Indictment.

Finally, while the *Gonzales* Court held that the CSA does not give the Attorney General power to regulate medical practice generally, it recognized that

[t]he statute and our case law amply support the conclusion that Congress regulates medical practice insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood. Beyond this, however, the statute manifests no intent to regulate the practice of medicine generally.

her prescription-writing powers to engage in illicit drug dealing. It sets forth in its opposition the factual basis for its contention that Dr. Norris's activities fell outside the usual course of professional practice. Dr. Norris, in her reply, counters those facts with a defense of her practices. But those factual arguments do nothing to advance the Defendant's claim that the Attorney General and the DEA have exceeded their legislative authority. Rather, those arguments underscore why criminal *allegations* that Dr. Norris wrote unauthorized prescriptions do not exceed the Attorney General's or the DEA's authority. Because, ultimately, it will be up to a jury (not the DOJ or the DEA) using objective evidence measured against state standards to decide whether the Government has presented enough evidence to establish that Dr. Norris's conduct was unauthorized.

Prosecution of physicians under Section 841 has been approved by the Supreme Court on at least two occasions. *Ruan*, 597 U.S. at 454; *United States v. Moore*, 423 U.S. 122, 124 (1975) ("[R]egistered physicians can be prosecuted under [Section] 841 when . . . their activities fall outside the usual course of professional practice."). And there have been many cases in the lower courts that have allowed

prosecutions of practitioners like doctors and pharmacists for violating Section 841 by acting for illegitimate purposes outside the usual course of professional practice. See, e.g., United States v. Simon, 12 F.4th 1, 24 (1st Cir. 2021) (noting that the authorization for "licensed health-care practitioners (typically, physicians)" to dispense controlled substances "is not absolute" because they may "face criminal liability 'when their activities fall outside the usual course of professional practice'" (quoting Moore, 423 U.S. at 124)); United States v. Sabean, 885 F.3d 27, 46–47 (1st Cir. 2018); United States v. Limberopoulos, 26 F.3d 245, 249 (1st Cir. 1994); United States v. Anderson, 67 F.4th 755, 764–65, 768–70 (6th Cir. 2023); United States v. Quinones, 635 F.3d 590, 594 (2d Cir. 2011); United States v. Zolot, 968 F. Supp. 2d 411, 428–29 (D. Mass. 2013) (collecting cases).

Finally, I address the Defendant's third argument that the delegation of rule-making authority to the Attorney General found in Section 821 is "neither sufficiently clear nor adequately explicit" to assure that Congress intended to allow the Attorney General or the DEA to criminalize a physician's conduct. Second Mot. at 3. In support of this claim, the Defendant cites Alabama Association of Realtors v. Department of Health and Human Services, 141 S. Ct. 2485 (2021). Alabama Association of Realtors involved a challenge to a nationwide eviction moratorium that the CDC imposed during the COVID-19 pandemic. The Supreme Court, refusing to continue a stay pending appeal, concluded that it was "difficult to imagine [the Alabama Association of Realtors] losing" given that the CDC had used its statutory authority to issue a regulation implementing an unprecedented nationwide moratorium on evictions after

Congress had declined to extend its own moratorium. Id. at 2488. It stated: "We

expect Congress to speak clearly when authorizing an agency to exercise powers of

'vast "economic and political significance." '" Id. at 2489 (quoting Util. Air Regul. Grp.

v. EPA, 573 U.S. 302, 324 (2014)). Other than offering the general rule, the Defendant

does not develop her argument or explain how the CDC's moratorium, which intruded

upon the state law property rights of landlords all over the country, is anything like

Section 1306.04(a), which merely parrots the CSA, refers to state law principles for

its contours, and has been used to support prosecutions of physicians for decades.

Alabama Association of Realtors is distinguishable from the present situation, and

the argument fails to persuade me to dismiss this indictment.

CONCLUSION

For the reasons stated above, I DENY the Defendant's motion to dismiss on

vagueness grounds without prejudice (ECF No. 65). I also **DENY** the Defendant's

motion to dismiss for exceeding congressional authority with prejudice (ECF No. 66).

SO ORDERED.

/s/ Nancy Torresen

United States District Judge

Dated this 11th day of January, 2024.

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